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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,611	09/24/2003	Erik H.F. Wong	28341/6248.10	5620

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT PAPER NUMBER

1614

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/669,611	Applicant(s) WONG ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41,44-51 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41,44-51 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-23-06</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicants' Amendment filed February 23, 2006 is acknowledged. New claim 54 is presented. Accordingly, claims 41, 44-51 and 54 are now under consideration.

An Information Disclosure Statement filed February 23, 2006 is further acknowledged and has been reviewed to the extent each is a proper reference on a U.S. patent.

Amendments to the Abstract are noted. The objection thereto is withdrawn.

In the last Office Action claims 41 and 44-51 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent 6,610,690.

The rejection is withdrawn because S,S-reboxetine is about 5-8 fold more potent than the reboxetine racemate with respect to inhibiting the reuptake of norepinephrine. Claim 1 of the patent is drawn to a compound having a pharmacological selectivity of serotonin (K_1)/norepinephrine (K_1) of at least about 5000. Therefore, racemic reboxetine is excluded. Claim 24 is drawn to an optically pure (S,S) reboxetine substantially free of (R,R) reboxetine.

Claims 41 and 44-51 were rejected in the last Office Action under 35 U.S.C. 112, second paragraph, because the metes and bounds of the recitation "and other somatoform disorders" cannot be precisely determined.

Because the specification describes and identifies such disorders on page 27 in a manner consistent with DSM-IV, the rejection of record under 35 U.S.C. 112, second paragraph, is withdrawn.

Claims 41 and 44-49 were rejected in the last Office Action under 35 U.S.C. 102(b) as being anticipated by Burrows et al., J. Clin. Psych. It was asserted Burrows teaches the administration of racemic reboxetine to treat dysthymia.

Applicants argue, according to DSM-IV, dysthymia is not a somatoform disorder and Burrows does not teach treatment of fibromyalgia comprising administering reboxetine.

There was no assertion in the rejection of record under 35 U.S.C. 102(b) that Burrows teaches a treatment for fibromyalgia. Claims 1 is interpreted to be drawn to treatment of fibromyalgia, as well as any one of the somatoform disorders that are exemplified on page 27, lines 13-16, of the specification. Because dysthymia is included among those disorders characterized as "somatoform" in the instant specification, the rejection of record is maintained and presently extended to include claim 51 and new claim 54. The commercial product is racemic reboxetine methanesulphonate and is well established in the prior art.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41, 44-51 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fallon et al., Psychopharmacology Bulletin.

Fallon teaches the administration of the selective serotonin reuptake inhibitor fluoxetine to treat types of hypochondriasis, a somatoform disorder according to DSM-

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IV. Fibromyalgia is included among somatoform disorders. The claims differ in that Fallon is silent concerning administration of reboxetine. However, reboxetine is a selective serotonin reuptake inhibitor with almost identical clinical indications as fluoxetine. Therefore, it would have been reasonable to expect reboxetine to be effective in the treatment of somatoform disorders since its mechanism of action closely parallels that of fluoxetine. The determination of optimal dosages, as well as modes of administration, are parameters well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

Suffin, S., US 2004/0059241, is cited to show further the state of the art. See claims 27 and 31, page 25.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marscel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

May 3, 2006

Phyllis Spivack
Phyllis Spivack

1614

PHYLLIS SPIVACK
PRIMARY EXAMINER